

**REMARKS**

Claims 1-36 are pending. Claims 1-18, 23-30, and 32-36 are currently under examination. It is believed that claims 19-22 and 31 have been inappropriately characterized in past communications as withdrawn, although not explicitly noted as such in the current Office Action.

Claims 1, 2, 7, 12, 19-22, and 29-35 are amended herein to recite “fumed.” Moreover, claims 19-22 are amended herein to recite “fumed alumina.” And, claims 20-22 are amended to require the recited concentrations.

Support for the present amendment is found in the specification as originally filed. More specifically, support for the recitation “fumed” is found at least at page 8, line 26; support for the recitation “fumed alumina” in Claims 19-22 is found at least at page 6, line 7; and support for the concentrations recited in Claims 20-22 is found at least at page 6, lines 8-10.

No new matter is introduced.

Applicants reserve the right to reintroduce cancelled subject matter, for example, in a later-filed continuing application.

Applicants would like to thank the Examiner for her reconsideration and withdrawal of earlier rejections under 35 U.S.C. §102 and §103. In the foregoing amendment and the following remarks, Applicants respond to the stated new grounds of rejection.

***Rejection of Claims under 35 U.S.C. §112, 2<sup>nd</sup> is Rendered Moot***

The Office rejected claims 8-11 under 35 U.S.C. §112, 2<sup>nd</sup> as allegedly being indefinite. According to the Office, there is insufficient antecedent basis for “fumed metal oxide” in claim 2. Office Action at page 2.

By the present amendment, claim 2 recites “fumed metal oxide,” therefore, the rejection is rendered moot.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

***Rejection of Claims under 35 U.S.C. §102(b) is Traversed or Rendered Moot***

The Office rejected claims 1-6, 12, and 15-18 as allegedly anticipated by U.S. Patent No. 6,730,230 (Cook). Office Action at page 3, lines 1-17. In view of the foregoing amendment and the following remarks, the rejection is traversed or rendered moot.

According to the Office, "Cook does not disclose, however, use of fumed silica ..." Office Action at page 4, lines 14-15; emphasis added.

Applicants respectfully disagree with the Office assertion regarding alleged anticipation by Cook. Nonetheless, by the present amendment, claims 1-6, 12, and 15-18 require the feature "fumed." Accordingly any asserted basis for the rejection is moot, and Applicants respectfully request that the rejection be withdrawn.

***Rejection of Claims under 35 U.S.C. §103(a) is Traversed***

The Office rejected claims 1-18, 23-30, and 23-28 as allegedly unpatentable over the combined teachings of Cook, Gun'ko *et al.*, Journal of Colloid and Interface Science, 192:166-178 (1997) (Gun'ko), and U.S. Patent No. 6,150,172 (Schmerr). Office Action at page 4, line 11 through page 5. In view of the foregoing amendment and the following remarks, the rejection is traversed or rendered moot.

Applicants note that, by the present amendment, all claims require the feature "fumed." And, as noted in Applicants' specification, for example at page 1 of the specification as originally filed, lines 5-7, "[t]he pathogenic prions are separated from biological materials by exposing the material to metal oxides and/or particulate silicon dioxide, including fumed metal oxides such as fumed silica." For example, in evaluating a plasminogen extraction using Al(OH)<sub>3</sub>, prion (*i.e.*, PrPSc) clearance of "approximately 3 logs" is obtained while plasminogen protein "[r]ecover[y] analysis indicated very little protein loss across this step." See, *e.g.*, specification at pages 15-16, Example 4.

Although the U.S. Supreme Court in *KSR v. Teleflex* rejected a "rigid approach" to the application of the recognized Teaching-Suggestion-Motivation test, the Court stated that there still must be some "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (U.S. 2007) (*quoting In re Kahn*, 78 USPQ2d 1329 (Fed. Cir. 2006)). Here, the Office appears to

believe that the requirement for rational underpinning is satisfied by its assertion of *prima facie* support for its obviousness rejection on pages 4 and 5 of the Office Action.

According to the Office, “Cook describes a method of using high density microparticles for the removal of pathogens ...” Office Action at page 3, lines 3-4. But, according to the Office, “Cook does not disclose, however, use of fumed silica ...” Office Action at page 4, lines 14-15; emphasis added. However, the Office states, “Gun’ko et al characterized fumed silica and its adsorption of proteins (see whole document). The authors [of Gun’ko] state that fumed silica in aqueous suspensions possesses a high adsorption ability for proteins (see Introduction). Thus, it would have been obvious to the ordinary artisan to use fumed silica in separating *any* protein, including prions, out of a solution.” Office Action at page 4, lines 18-20; emphasis added. Finally, Schmerr is cited by the Office for allegedly disclosing various features of several dependent claims. Office Action at page 5, lines 3-15.

In the passages from the Office Action reproduced above, it is apparent that the Office believes that Gun’ko’s statement “that fumed silica in aqueous suspensions possesses a high adsorption ability for proteins” is sufficient to suggest to one of ordinary skill in the art that Gun’ko’s discussion of fumed silica would be combined with asserted teachings of Cook regarding Cook’s method of removing pathogens from a solution. Apparently, the Office takes this position because the method of Cook involves using high density microparticles. However, in view of the overall teaching of Cook as discussed below, such an understanding on the part of a person of ordinary skill in the art is simply not tenable at least because there is no common problem to be solved. In this regard, Applicants’ point out that Gun’ko (see, e.g., Gun’ko at page 167, left column, lines 40-47) discusses technical considerations regarding protein adsorption on the surface of fumed silica aggregates, while Cook discusses removal of pathogens with a pathogen-specific “reactant,” i.e., not by direct action of any support material (e.g., “HDM”) discussed therein. Moreover, the discussion of Cook in relation to specific reactants appears to teach away from use of materials operating on a more general principle, or at least fails to teach or suggest any such use of materials discussed therein as “supports.” See, e.g., Cook, at Col. 7, lines 45-50. Accordingly, the Office has failed to provide the “rational underpinning” required by KSR. The following comments including discussions of Cook and Gun’ko support this conclusion.

Applicants point out that Cook discloses "high density microparticles having bound thereto a reactant which specifically binds to the target pathogen ..." Cook at Col. 3, lines 1-2; emphasis added. And according to Cook, "[s]uitable reactants include monoclonal and polyclonal antibodies (including antibody fragments) that specifically bind to the target pathogen, or synthetic molecules designed or selected to have high affinity for target pathogens. See, e.g., Cook at Col. 7, lines 29-33. For example, according to Cook, "[a] plurality of high density microparticles ("HDM") having a reactant such as an anti-pathogen antibody, bound thereto are mixed with the sample." Cook at Col. 2, lines 58-62.

Thus, the high density microparticles in Cook, which require a reactant group bound thereto, are discussed as providing a means of settling out of a solution (by differential gravity) a specific reactant/target pathogen complex. The fact that any discussion in Gun'ko involves fumed silica or, as stated by the Office, "fumed silica in aqueous suspensions possesses a high adsorption ability for proteins" does not teach or suggest any such combination of Cook and Gun'ko. Although a suggestion to combine elements of multiple references may be found outside of the references themselves, some suggestion must be found in the references or in the knowledge in the art. In this regard, it is instructive to note that the Federal Circuit recently found jury instructions proper (where the instructions included a statement that "there must have been some suggestion for a person skilled in the art to make the combination covered by the claims of the patent in issue in order for the claims to have been obvious") so long as the instructions also defined motivation as potentially arising "from common knowledge, or common sense of the person of ordinary skill in the art, without any specific hint or suggestion in a particular reference." *Rentrop v. Spectranetics* (Court of Appeals for the Federal Circuit, 07-1560 at page 7, line 3 through page 8, line 3; Decided December 18, 2008).

It is Applicants' position that the choice of any teaching in Cook for any proposed combination with any teaching of Gun'ko would be considered random and arbitrary by one of ordinary skill in the art. Accordingly, it is Applicants' position that the Office has impermissibly used hindsight gained from reading Applicants' specification to propose the combination of references asserted in support of the current rejection. No motivation to combine any teachings of the references can be found in the references themselves. Accordingly, a person of ordinary

skill in the art would not have combined any teachings of the references to obtain Applicants' claimed invention.

Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

**CONCLUSION**

Applicants believe that all rejections have been rendered moot or traversed and that the claims are in condition for immediate allowance. Early notice to that effect is earnestly solicited.

The Office is invited to contact the undersigned at (202) 857-4507 with any question she may have concerning this submission.

Respectfully submitted,

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